

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effectiveness of Plantago major extract on the healing of diabetic foot ulcer and bedsore

Protocol summary

Study aim

Determining the effectiveness of Plantago major topical gel in the healing of diabetic foot ulcer and bedsore

Design

Two arm parallel group randomised trial with control group

Settings and conduct

The study will be performed in Al-Zahra hospital of Isfahan. Patients with the inclusion criteria will be randomly assigned to drug (Plantago major) or control groups. For patients in drug group, Plantago extract 10% topical gel will be applied for two weeks, while for patients of control group, specific dressing (Aquacel-Ag) will be used for two weeks. Before any intervention, the wound size as the product of the longest length and width as well as the presence or absence of erythema around the wound will be determined and recorded. At the end of 7th and 14th day of intervention, the percent of wound size reduction and the erythema status will be recorded. Furthermore, the number of cases with complete wound healing during the study will be recorded for both groups. Finally, the mentioned variables will be compared between the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age of 18 years-old or more 2. Diabetic foot ulcer grade 1 or 2 or bedsore stage 2 or 3
Exclusion criteria: 1. Smoking 2. Coagulopathy

Intervention groups

Drug Group: Plantago extract 10% topical gel (made by faculty of pharmacy of Isfahan university of medical sciences), once daily concurrent with routine wound care including irrigation with normal saline solution, dressing, and antibiotic administration, if necessary, for two weeks
Control Group: Specific dressing (Aquacel-Ag, made by Convatec company, USA), once daily concurrent with routine wound care including irrigation with normal saline solution, dressing, and antibiotic administration, if necessary, for two weeks

Main outcome variables

1. The percent of decrease in the wound size 2. The number of cases of complete wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N12**

Registration date: **2020-07-19, 1399/04/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-19, 1399/04/29**

Update count: **0**

Registration date

2020-07-19, 1399/04/29

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty
Scientific title
Evaluation of the effectiveness of Plantago major extract on the healing of diabetic foot ulcer and bedsore

Public title
Effect of Plantago major on wound healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic foot ulcer grade 1 or 2 Bedsore stage 2 or 3
Exclusion criteria:
Smoking Use of Anticoagulant Drugs Within the Last 3 Months

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method will be used. For this, patients with even and odd medical profile numbers, respectively, will be assigned to drug and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Vice-chancellery for research, Isfahan University of Medical Sciences, Hezar-Jerib Avenue
City
Isfahan
Province
Isfahan

Postal code
8174673461
Approval date
2020-04-15, 1399/01/27
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.146

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcer
ICD-10 code
E11.621
ICD-10 code description
Type 2 diabetes mellitus with foot ulcer

2

Description of health condition studied
Bedsore
ICD-10 code
L89
ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Percent of Decrease in Ulcer Size
Timepoint
Baseline, 7 and 14 Days after Initiation of Intervention
Method of measurement
Ruler

2

Description
The Number of Cases of Complete Ulcer Healing
Timepoint
During the Intervention
Method of measurement
Observation

Secondary outcomes

1

Description
The Number of Cases with Peri-Ulcer Erythema
Timepoint
Baseline, 7 and 14 Days after Initiation of Intervention
Method of measurement
Observation

Intervention groups

1

Description

Intervention group: 10% Plantago major Topical Gel, made in faculty of Pharmacy of Isfahan university of medical sciences, Once Daily, with wound irrigation and dressing, for 14 Days

Category

Treatment - Drugs

2

Description

Control group: Special dressing (made in Convatec company, USA), once daily, with wound irrigation, for 14 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Rasool Soltani

Street address

Al-Zahra hospital, Soffeh Blvrd

City

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alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice-chancellery for Research, Isfahan university of medical sciences, Hezar-Jerib Ave.

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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Rasool Soltani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position
Associate professor
Latest degree
Specialist
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Faculty of Pharmacy, Isfahan University of Medical Sciences, Hezar-Jerib Ave.
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no necessity.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available